DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

OTSG Regulation
No. 15-82

1 May 1990

Boards, Commissions, and Committees

HUMAN SUBJECTS RESEARCH REVIEW BOARD SUBCOMMITTEE FOR REVIEW OF MATERIEL TEST PLANS AND PROTOCOLS

1. ESTABLISHMENT. This regulation establishes the Human Subjects Research Review Board (HSRRB) Subcommittee for Review of Materiel Test Plans and Protocols, hereinafter referred to as the subcommittee, as permitted under OTSG Regulation 15-2.

2. APPLICABILITY. This regulation applies to the subcommittee and principal investigators and test directors submitting protocols and test plans to the subcommittee.

a. This regulation is not intended to supersede the requirement for health hazard or other safety review required by DA regulations.

b. Acceptability of protocols and test plans will be in terms of appropriate regulations, applicable law, and standards of conduct and practice.

3. REFERENCES.

a. Required publications.

(1) AR 70-25 (Use of Volunteers as Subjects of Research).

(2) OTSG Reg 15-2 (Human Subjects Research Review Board).

b. Related publications.

(1) AR 25-400-2 (The Modern Army Recordkeeping System (MARKS)).

(2) AR 70-10 (Test and Evaluation During Development and Acquisition of Materiel).

(3) AR 70-65 (Management of Controlled Substances, Ethyl Alcohol, and Hazardous Biological Substances in Army Research, Development, Test, and Evaluation Facilities).

(4) AR 385-16 (System Safety Engineering and Management).

(5) Code of Federal Regulations, Title 45, Part 46 (45 CFR 46) (Protection of Human Subjects).

(6) DA PAM 70-21 (The Coordinated Test Program (CTP)).

(7) DOD Directive 3216.2 (Protection of Human Subjects in DOD-Supported Research).

4. PURPOSE.

a. U.S. Army agencies not operating a human use committee may submit protocols and test plans for research, development, test, and evaluation (RDTE) of weapons systems, equipment, and materiel directly or indirectly involving the use of human subjects to the Human Use Review and Regulato Affairs Office, U.S. Army Medical Research and Development Command, Fort Detrick, Frederick, MD 21701-5012, for review by the subcommittee. The subcommittee chairperson will be the Chief, Human Use Review and Regulatory Affairs Office or his or her designee. Protocols and test plans that involve the use of human subjects may not be initiated until all necessary approvals and the informed consent of the subjects, when necessary, have been obtained.

b. The approving official may not approve protocol and test plans for which he or she is the principal or associate investigator or test director. A higher echelon of command must review and approve such protocols or test plans.

c. No subcommittee member may vote on any protocol or test plan in which the member serves as the principal investigator or test director, associate investigator, or representative from the directorate or laboratory sponsoring the protocol or test plan.

d. The subcommittee may invite persons with special competence to assist in the review of complex issues that require expertise beyond that available on the subcommittee. These persons may not vote with the subcommittee.

5. RESPONSIBILITIES.

a. The Chairperson, HSRRB, or his or her designee--

(1) Will be the approving official.

(2) Will establish and appoint members to the subcommittee.

(3) Will have the authority to approve the use of human subjects in protocols and test plans and may--

(a) Accept, reject, or waive recommendations by the subcommittee.

(b) Require additional safeguards.

(c) Disapprove the protocol or test plan.

(d) Refer the protocol or test plan to a higher echelon approving authority and review committee, as appropriate.

(4) Will not have the authority to--

(a) Reduce the safeguards or conditions imposed by the subcommittee.

(b) Approve a protocol or test plan for which the subcommittee has recommended disapproval.

b. The HSRRB subcommittee chairperson will--

(1) Provide an administrative review of all protocols and test plans using human subjects.

(2) Report all administrative approvals (those not requiring formal subcommittee action) to the subcommittee in the minutes of the next subcommittee meeting.

(3) Call and conduct meetings of the subcommittee.

(4) Receive copies of proposed protocols and test plans that have been peer-reviewed and received safety and health hazard assessment, as appropriate, and distribute them to members of the subcommittee.

(5) Submit minutes of all meetings to the approving official.

(6) Maintain a record file of all approved protocols and test plans and all supporting documents.

(7) Act as necessary to sustain subcommittee functions and composition (to include arranging for member selection, approval, and appointment) in accordance with AR 70-25. The name of a prospective

member or successor will be submitted to the approving official for approval. A record of approval and copy of the member's curriculum vita will be kept on file.

(8) Ensure that subcommittee members are provided minutes, information and training experiences sufficient to enable the subcommittee to function in an informed manner.

(9) Recommend approval of protocols and test plans upon concurrence from a majority of the subcommittee members.

c. The principal investigator or test director will--

(1) Provide all documentation and perform all tasks required by AR 70-25, paragraph 3-2k, and as requested by the subcommittee to the chairperson, including obtaining certification of scientific validity, safety release, and/or health hazard assessment for the protocol or test plan prior to its submission to HURRAO.

(2) Whenever feasible, present and discuss protocols and test plans at subcommittee meetings and answer subcommittee members' questions.

(3) When informed consent is deemed necessary, provide the volunteer with a completed copy of his or her DA Form 5303-R (Volunteer Agreement Affidavit).

(4) Promptly report to the subcommittee any significant injuries to test participants, unexpected problems and proposed changes in the protocols and test plans.

d. The subcommittee will--

(1) Maintain a current list of its members. Members will be identified by name and representative capacity, along with earned degrees, board certifications and licenses, and experiences, as appropriate. The information will be complete enough to describe each member's chief expected contributions to subcommittee reviews.

(2) Determine that all protocols and test plans involving human subjects conform with AR 70-25.

(3) Establish the level of risk associated with test plans according to guidelines established in AR 70-25 (for example, minimal risk; greater than minimal risk).

(4) Make the following recommendations to the approving official on protocols and test plans determined to have a minimal level of risk: Approval, approval with modification, deferral, disapproval, or exempt from further human use review.

(5) Those protocols and test plans determined to have a greater than minimal level of risk will be referred to the HSRRB for further

review. HSRRB recommendations will be forwarded to The Surgeon General for approval.

(6) Utilize functional area advisers, when necessary, to ensure that specialty areas of interest have been addressed during reviews.

(7) Review associated standing operating procedures and test plans.

(8) When deemed necessary, ensure that volunteers are adequately informed concerning the risks involved with their participation in the proposed test.

(9) Conduct continuing review of protocols and test plans at intervals determined appropriate by the subcommittee according to the degree of risk, but not less than once per year.

(10) Perform initial and continuing reviews for referred test plans involving the use of human subjects.

(11) Determine when site visits to facilities by an authorized representative of the subcommittee are deemed necessary.

(12) Review after-action documentation to ensure that completed tests were conducted as approved.

6. COMPOSITION.

a. Membership will include only full-time Federally employed persons.

b. The subcommittee will have at least five voting members, including the chairperson. Members will have diverse backgrounds to ensure thorough review of protocols and test plans involving human volunteers as subjects.

c. Members should be sufficiently qualified through experience and expertise and have the professional competency to review protocols and test plans and/or be interested parties concerned with the volunteer subject's welfare.

d. The subcommittee will include at least one member whose primary concerns are nonscientific; for example, lawyers, ethicists, and members of the clergy.

e. A physician will be included as a voting member of the subcommittee.

f. The subcommittee will include at least one member who is not otherwise affiliated with the organization conducting the test and who is not part of the immediate family of a person affiliated with the organization conducting the test. This requirement may be met by appointing a member of an institution or organizational unit not subject to the immediate authority of the approving official.

7. DIRECTION AND CONTROL.

a. The subcommittee--

(1) Is specifically concerned with the implementation of a human subjects review process consistent with AR 70-25.

(2) May meet at the call of the chairperson to review protocols and test plans in a timely manner and to stay current as a body on any doctrinal changes that may affect its decisions.

(3) Will review proposed protocols and test plans at meetings attended by a quorum. A quorum will consist of a majority of voting members or their alternates. For the protocol or test plan to be recommended for approval, it will receive a favorable vote from a majority of those members present.

(4) Will conduct the initial and annual review of the protocol or test plan or at appropriate intervals as deemed necessary by the subcommittee, but not less than once per year for greater than minimal risk. Findings and actions by the subcommittee will be reported to the principal investigator or test director and the approving official.

(5) Will determine those projects that must be--

(a) Reviewed more often than annually.

(b) Verified from sources other than the investigators or test directors that no material changes have occurred since the previous subcommittee review.

(6) Will require prompt reporting to the subcommittee of proposed changes in approved protocols and test plans. No changes will be made on approved projects nor tests initiated on changed protocols and test plans without further review and approval by the subcommittee and the approving official except to eliminate immediate hazards to the subject or test personnel.

(7) Will require prompt reporting to the subcommittee or approving official of unexpected problems involving risks to the subjects or others.

(8) Will report to the approving official any serious or continuing non-compliance with subcommittee requirements and determinations by investigators.

(9) Will have the authority to observe or have a third party observe, where applicable, the volunteer consent process, and the test.

(10) May stipulate safeguards or special conditions to a protocol or test plan.

b. Protocols and test plans to be reviewed by the subcommittee will--

(1) Be submitted to the chairperson by the principal investigator or test director for subcommittee review.

(2) Include any actions taken by the principal investigator or test director in response to recommendations arising from the review of the test plan for safety or scientific validity.

c. The chairperson will notify the principal investigator or test director as soon as action has been taken on the protocol or test plan.

d. Criteria for recommendation for protocol and test plan approval will include--

(1) Evaluation of risks and benefits for the proposed test. The subcommittee will consider only those that may result from the test.

(2) Determination that all applicable AR 70-25 requirements are met; including the following:

(a) Risks to subjects are minimized by using procedures that are consistent with sound investigation and safety design, using current scientific standards and procedures, and do not unnecessarily expose subjects to risk.

(b) Risks to subjects are reasonable.

(c) In the assessment of the procedure used for the selection of subjects, the subcommittee will take into account the purpose of the test and the setting in which the test will be conducted.

(d) When informed consent is deemed necessary, the DA Form 5303-R for the prospective subject is properly documented and written in language easily understood by the subject.

(e) The protocol or test plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, when appropriate.

(f) Adequate provisions exist to protect the privacy of subjects and to maintain the confidentiality of data, when appropriate.

e. Suspension or termination of an approved test plan.

(1) The chairperson, approving official or the subcommittee will have the authority to suspend or end an approved protocol or test plan that--

(a) Is not being conducted as outlined in the approved protocol or test plan.

(b) Has been associated with unexpected serious harm to subjects.

(2) Suspension or terminations of protocols and test plans will include a statement of the reasons for the subcommittee's action. They will be reported promptly to the principal investigator or test director and approving official.

f. Voting procedures.

(1) Voting will be conducted by voice vote by permanent voting members of the subcommittee.

(2) The chairperson is a voting member of the subcommittee.

g. Subcommittee records.

(1) The subcommittee will prepare and maintain adequate documents on subcommittee activities, including--

(a) Copies of all protocols and test plans reviewed; scientific evaluations and safety releases that accompany the proposals; approved sample consent documents, if applicable; progress reports submitted by investigators or test directors, and reports of injuries or adverse reactions.

(b) Minutes of subcommittee meetings showing attendance; actions taken by the subcommittee; the vote on these actions, including the number of members voting for, against, and abstaining a decision; the basis for recommending changes, deferring or disapproving the test; and a written summary of the discussion of controverted issues and their resolution. Reports of any administrative approvals will also be included in the subcommittee minutes.

(c) Copies of all correspondence between the subcommittee and the principal investigator or test director.

(d) A list of subcommittee members.

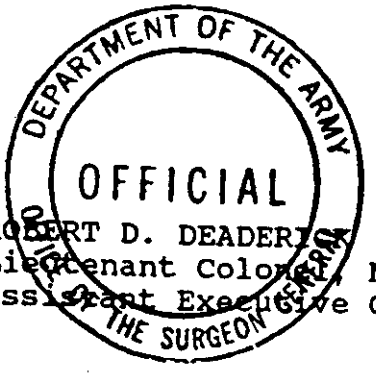
(e) Written procedures for the subcommittee.

(2) The records required by this regulation are permanent records as defined in AR 25-400-2. These permanent records are maintained at the Human Use Review and Regulatory Affairs Office, USAMRDC.

8. ADMINISTRATIVE SUPPORT. Administrative support will be provided by the Human Use Review and Regulatory Affairs Office, USAMRDC.

SGRD-HR (16 Apr 90)

FOR THE SURGEON GENERAL:



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